

EXHIBIT A

Template

FORM - Non Conformity Reporting		
Status:Published		Document ID: 1503
DATE EFFECTIVE 05/02/2017	APPROVED BY Quality Assurance Manager	PAGE 1 OF 2

Instructions: For use on non-conformities discovered during the course of casework. The Principal Investigator must investigate the issue and complete this form. Submit to the Quality Assurance Manager; further action may be required.

Case Number(s) Involved: FB18-02323

Date of Occurrence: 5/15/18-5/16/18

Date of Discovery: 5/22/18

Description of non-conformity (please be specific):

A male donor profile was deduced using STRmix from swab of "slide, hammer and safety". This profile matches the Labtypes profile #91485.

How was this non-conformance identified? (choose one)

Other

If "Other" please provide details: During a LDIS search of the male donor profile

Results of the Root Cause analysis (attach Root Cause worksheets):

KCM (Labtypes profile #91485) was on the pre-amp rotation the week of 5/14/18-5/18/18. The extraction, quantification, initial and replicate amplification all occurred during this week. KCM however did not perform any of these procedures, nor did they witness them. No lab cleanup was performed during this week as well. It cannot be determined at what point DNA from the analyst came in contact with the sample, but it most likely occurred during the pre-amplification procedures by means of the lab supplies such as pipette tips, tubes or plates.

Immediate actions taken to correct the issue (Be specific. Include location of documentation):

The combined results from the swab of "slide, hammer and safety" will be deemed inconclusive and no comparisons will be made. An LR check using the lab types profile was performed against the mixture from the swab of "trigger/trigger guard" to determine if they are a contributor to this sample (LR fell into the uninformative range). The electropherograms with the associated test batches were visually examined to determine if this profile could be a contributor to any other sample, which it did not appear to be.

Recommended actions taken to correct the Root Cause of the issue (Be specific. Include location of documentation):

The analyst will be more attentive in the future with regards to lab hygiene when handling lab supplies/instruments/samples. Analyst will ensure all PPE is properly worn and gloves are cleaned with bleach before handling anything in the lab, as well as using bleach and ethanol to clean down their work area before and after each use.

#91485

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Comments:

Principal Investigator (Print): AGL

Signature:  Date: 6/8/18

Analyst involved (Print): KCM

Signature:  Date: 6/8/2018

Immediate Supervisor, if applicable (Print): JR

Signature:  Date: 6/8/2018

Review by QA Manager:

- ☒ No additional information/corrections required
- ☒ Form **does not** need to be forwarded to the OCME Root Cause Analysis Officer
- ☐ Additional information/corrections **required**
- ☐ Form **has been** forwarded to the OCME Root Cause Analysis Officer

Comments:

Signature:  Date: 8/3/18
9/20/18

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